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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/081,333

02/22/2002

Lorri Riley

RILO.95943

9812

27910

7590

04/27/2006

STINSON MORRISON HECKER LLP
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EXAMINER

TRAN, SUSAN T

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 04/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/081,333	RILEY, LORRI	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u>04/24/06</u> . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5-11 and 19-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a topical nail formulation with an applying agent, does not reasonably provide enablement for any applying agent. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." In *In re Wands*, these factors include:

- 1) The nature of the invention;
- 2) The state of the prior art;
- 3) The level of one of ordinary skill;
- 4) The level of predictability in the art;
- 5) The breadth of the claims;
- 6) The amount of direction or guidance provided by the inventor;
- 7) The existence of working examples; and

8) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation. These factors are discussed in detailed as follow:

1) The nature of the invention: the invention is directed to a topical nail formulation, and a method of making same.

2) The state of the prior art: the state of the art is high in term of using topical nail formulation containing antifungal agent.

3) The level of one of ordinary skill: the ordinary skill in the art is high (MD level technology).

4) The level of predictability in the art: there is predictability in the art of the ability of a topical nail formulation containing antifungal agent.

5) The breadth of the claims: instant independent claims are broad with respect to the use of an applying agent.

6) The amount of direction or guidance provided by the inventor: applicant's specification describes that the applying agent may be an ointment, nail polish, or a lotion. However, the specification does not provide any guidance and/or direction as to what ointment, what nail polish, or what lotion can be added to obtain a topical nail formulation. In other word, will all lotion, nail polish, and ointment in the cosmetic/pharmaceutical art constitute as the "applying agent" to enable one of ordinary skill in the art to obtain a topical nail formulation?

7) The existence of working examples: there is one working example, however, it fails to show any specific ointment.

8) The quantity of experimentation needed to make or use the invention based on the content of the disclosure: it would require an undue experimentation by one of ordinary skill in the art to select a specific applying agent to achieve the claimed topical nail formulation.

Claims 12-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a topical nail formulation with an applying agent, does not reasonably provide enablement for a method of treating a nail of a patient using any applying agent. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue."

According to *In re Wands*, the factors are discussed in detailed as follow:

1) The nature of the invention: the invention is directed to a method for treating a nail of a patient.

2) The state of the prior art: the state of the art is high in term of treating nail that has a fungal infection.

3) The level of one of ordinary skill: the ordinary skill in the art is high (MD level technology).

4) The level of predictability in the art: there is predictability in the art of the ability of treating nail infection.

5) The breadth of the claims: instant independent claims are broad with respect to the use of an applying agent.

6) The amount of direction or guidance provided by the inventor: applicant's specification discloses a topical nail formulation comprising an ointment (see example 1). However, the specification fails to point out what constitutes an ointment, or what type of ointment being used. Accordingly, the amount of direction or guidance provided by the inventor is unclear, and insufficient.

7) The existence of working examples: there is one working example, however, it fails to show any specific ointment that results in the claimed treatment.

8) The quantity of experimentation needed to make or use the invention based on the content of the disclosure: it would require an undue experimentation by one of ordinary skill in the art to select a specific applying agent to achieve a nail formulation for the treatment of nail fungal infection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5-21 are rejected because the limitation "applying agent" recited in the claims is unclear. While applicant's specification describes the applying agent may be an ointment, a lotion, or a nail polish, it is unclear if the agent is separately added to the formulation or if the "formulation" itself is in the form of an ointment, lotion, or nail polish. It is noted that the formulation being claimed is in a topical nail form, namely, a nail polish. In other word, what constitutes a nail polish (as an applying agent) to obtain a nail polish (as a formulation)?

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R from 6:00 am to 4:30 pm.

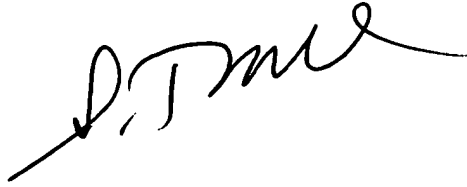
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Art Unit: 1615

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'S. Tran', with a stylized, cursive flourish extending to the right.

S. Tran
Patent Examiner
AU 1615